

Patent
10/086,585**IN THE CLAIMS:**

Please cancel Claims 8 and 11 without prejudice and without disclaimer of subject matter.

Please amend Claims 1, 9, 12, 14 and 15 as indicated.

1. (Currently Amended) A device to treat tissue while preventing tissue damage to adjacent tissue, comprising:

an ablation catheter, wherein the catheter includes:

a guidewire lumen;

a supply lumen; and

a return lumen;

a tubular introducer sheath for the ablation catheter, the introducer sheath at least partially contacting tissue to be protected, wherein said ablation catheter is inserted through and extends past a distal end of the introducer sheath, and further wherein, in use, the device is adapted to be positioned such that the ablation catheter contacts tissue to be treated and the introducer sheath contacts tissue to be protected;

a heater disposed adjacent or within the introducer sheath, the heater thermally coupled to the tissue;

a source of cryofluid having a supply tube and a return tube, the supply tube coupled in fluid communication to the supply lumen and the return tube coupled in fluid communication to the return lumen; and

a control unit for the heater.

2. (Original) The device of claim 1, wherein the heater is a resistive heater.

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3. (Withdrawn) The device of claim 1, wherein the heater includes an inlet tube fluidically coupled to an interior of the introducer, and at least one outlet orifice disposed in the introducer.

4. (Withdrawn) The device of claim 1, wherein the heater includes an inlet sleeve with an input for a body fluid at a distal end of the introducer sheath, wherein the inlet sleeve is fluidically coupled to an interior of the introducer, and at least one outlet orifice disposed in the introducer.

5. (Withdrawn) The device of claim 4, wherein the inlet sleeve has an annular shape along a portion thereof.

6. (Original) The device of claim 2, wherein the resistive heater is disposed on a sleeve, the sleeve concentric with the introducer sheath.

7. (Original) The device of claim 6, wherein the resistive heater is helically wound on the sleeve.

8. (Canceled)

9. (Currently Amended) The device of claim 8, wherein the guidewire lumen extends from a proximal end of the ablation catheter to a distal end of the ablation catheter.

10. (Original) The device of claim 1, further comprising at least one marker band disposed on the ablation catheter to locate a working region of the device at a desired location.

11. (Canceled)

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12. (Currently Amended) The device of claim 11, wherein the cryofluid is a perfluorocarbon.

13. (Original) The device of claim 12, wherein the cryofluid is Galden® fluid.

14. (Currently Amended) The device of claim 11, wherein the cryofluid is DMSO.

15. (Currently Amended) The device of claim 11, wherein the cryofluid is D-limonene.

16. (Original) The device of claim 1, further comprising a gear pump for circulating the cryofluid.

17. (Original) The device of claim 16, wherein the gear pump is one selected from the group consisting of a radial spur gear pump and a helical tooth gear pump.

18. (Withdrawn) A method of treating atrial fibrillation while preventing tissue damage to the atrial septum, comprising:

inserting a trocar wire capable of rupturing the atrial septum from the femoral vein into the right atrium;

forming a hole using the trocar wire in the atrial septum between the right atrium and the left atrium;

inserting an introducer sheath into the hole, the introducer sheath at least partially contacting the atrial septum;

inserting a guide wire through the introducer sheath into the right atrium and left atrium and further into a pulmonary vein;

disposing an ablation catheter over the guidewire into a volume defined by the joint of the left atrium and the pulmonary vein;

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flowing a cryofluid into a balloon disposed within the ablation catheter to ablate tissue adjacent the joint of the left atrium and the pulmonary vein; and
operating and controlling a heater disposed adjacent or within the introducer sheath, the heater thermally coupled to the atrial septum.

19. (Withdrawn) The method of claim 18, wherein the operating and controlling a heater including providing power to a resistive heater.

20. (Withdrawn) The method of claim 18, wherein the operating and controlling a heater includes flowing a warming fluid into an inlet tube fluidically coupled to an interior of the introducer sheath, and flowing the warming fluid out of at least one outlet orifice disposed in the introducer sheath.

21. (Withdrawn) The method of claim 18, wherein the operating and controlling a heater includes allowing a body fluid to flow in an inlet sleeve having an input for the body fluid at a distal end of the introducer sheath, wherein the inlet sleeve is fluidically coupled to an interior of the introducer, and allowing the body fluid to flow out of the at least one outlet orifice disposed in the introducer.

22. (Withdrawn) The method of claim 18, wherein the cryofluid is selected from the group consisting essentially of Galden® fluid, DMSO, and d-limonene.

23. (Withdrawn) The method of claim 18, further comprising circulating the cryofluid with a gear pump.

24. (Withdrawn) The method of claim 23, wherein the gear pump is one selected from the group consisting of a radial spur gear pump and a helical tooth gear pump.

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25. (Withdrawn) A method of performing a cryosurgery while preventing tissue damage to the point of insertion, comprising:

percutaneously forming an insertion hole in a vessel of a patient;
inserting an introducer sheath into the insertion hole, the introducer sheath at least partially contacting tissue at the insertion hole;
inserting a cryogenic catheter through the introducer sheath;
disposing the cryogenic catheter at a predefined location;
flowing a cryogenic liquid into the cryogenic catheter; and
operating and controlling a heater disposed adjacent or within the introducer sheath, the heater thermally coupled to the tissue at the insertion hole.

26. (Withdrawn) The method of claim 25, wherein the operating and controlling a heater including providing power to a resistive heater.

27. (Withdrawn) The method of claim 25, wherein the operating and controlling a heater includes flowing a warming fluid into an inlet tube fluidically coupled to an interior of the introducer sheath, and flowing the warming fluid out of at least one outlet orifice disposed in the introducer sheath.

28. (Withdrawn) The method of claim 25, wherein the operating and controlling a heater includes allowing a body fluid to flow in an inlet sleeve having an input for the body fluid at a distal end of the introducer sheath, wherein the inlet sleeve is fluidically coupled to an interior of the introducer, and allowing the body fluid to flow out of the at least one outlet orifice disposed in the introducer.

29. (Withdrawn) The method of claim 25, wherein the fluid is selected from the group consisting essentially of Galden® fluid, DMSO, and d-limonene.

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30. (Withdrawn) The method of claim 25, further comprising circulating the cryofluid with a gear pump.

31. (Withdrawn) The method of claim 30, wherin the gear pump is one selected from the group consisting of a radial spur gear pump and a helical tooth gear pump.

32. (Withdrawn) A method of reducing atrial fibrillation, comprising:
inserting a catheter at least partially into the heart, the catheter having a cold balloon, a portion of the balloon located in the left atrium and a portion of the balloon located in a pulmonary vein; and
inflating the cold balloon with a working fluid including DMSO such that an exterior surface of the cold balloon is in contact with at least a partial circumference of the portion of the pulmonary vein adjacent the left atrium, the working fluid having a temperature in the range of about -10°C to -100°C.

33. (Withdrawn) The method of claim 32, wherin the working fluid is circulated by a gear pump.

34. (Withdrawn) The method of claim 33, wherin the gear pump is one selected from the group consisting of a radial spur gear pump and a helical tooth gear pump.

35. (Withdrawn) A method of reducing atrial fibrillation, comprising:
inserting a catheter at least partially into the heart, the catheter having a cold balloon, a portion of the balloon located in the left atrium and a portion of the balloon located in a pulmonary vein; and
inflating the cold balloon with a working fluid including d-limonene such that an exterior surface of the cold balloon is in contact with at least a partial circumference of the portion of the

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pulmonary vein adjacent the left atrium, the working fluid having a temperature in the range of about -10°C to -100°C.

36. (Withdrawn) The method of claim 35, wherein the working fluid is circulated by a gear pump.

37. (Withdrawn) The method of claim 36, wherein the gear pump is one selected from the group consisting of a radial spur gear pump and a helical tooth gear pump.

38. (Withdrawn) A method of reducing restenosis after angioplasty in a blood vessel, comprising:

inserting a catheter into a blood vessel, the catheter having a balloon, the balloon having at least one pore formed therein; and

inflating the balloon with a working fluid including DSMO such that an exterior surface of the balloon is in contact with at least a partial inner perimeter of the blood vessel, the working fluid having a temperature in the range of about -10°C to -100°C.

39. (Withdrawn) A method of reducing restenosis after angioplasty in a blood vessel, comprising:

inserting a catheter into a blood vessel, the catheter having a balloon, the balloon having at least one pore formed therein; and

inflating the balloon with a working fluid including d-limonene such that an exterior surface of the balloon is in contact with at least a partial inner perimeter of the blood vessel, the working fluid having a temperature in the range of about -10°C to -100°C.

40. (Withdrawn) A device to perform a cryo-ablation treatment while allowing blood perfusion, comprising:

a catheter shaft having a supply lumen and a return lumen;

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an annular ring balloon fluidically coupled to the catheter shaft, the annular ring balloon having a fluid inlet coupled to the supply lumen, and a fluid outlet coupled to the return lumen, the fluid inlet displaced relative to the fluid outlet, a plane of the annular ring balloon substantially normal to the catheter shaft when inflated; and

a source of working fluid, the source having an inlet coupled to the return lumen and an outlet coupled to the supply lumen.

41. (Withdrawn) The device of claim 40, wherin the fluid inlet is displaced in a proximal direction relative to the fluid outlet.

42. (Withdrawn) The device of claim 40, wherein the source of working fluid includes a gear pump.

43. (Withdrawn) A device to perform a cryo-ablation treatment while allowing blood perfusion, comprising:

a catheter shaft having a catheter supply lumen and a catheter return lumen;
an annular ring balloon fluidically coupled to the catheter shaft, the annular ring balloon having a balloon supply lumen coupled to the catheter supply lumen, and a balloon return lumen coupled to the catheter return lumen, an inlet for the balloon supply lumen displaced relative to an outlet of the balloon return lumen, a plane of the annular ring balloon substantially normal to the catheter shaft when inflated; and

a source of working fluid, the source having an inlet coupled to the catheter return lumen and an outlet coupled to the catheter supply lumen.

44. (Withdrawn) A method of reducing atrial fibrillation, comprising:
inserting a catheter at least partially into the heart, the catheter having an annular ring balloon disposed near a distal portion thereof, a portion of the annular ring balloon located in the left atrium and a portion of the annular ring balloon located in a pulmonary vein; and

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inflating the annular ring balloon with a working fluid such that an exterior surface of the annular ring balloon is in contact with at least a partial circumference of the portion of the pulmonary vein adjacent the left atrium, the working fluid having a temperature in the range of about -10°C to 100°C.

45. (Withdrawn) The method of claim 44, wherein the working fluid is selected from the group consisting essentially of: DMSO, d-limonene, Galden fluid, and a perfluorocarbon-containing fluid.

46. (Withdrawn) The method of claim 44, wherein the inflating includes circulating the working fluid with a source of working fluid having a gear pump.

47. (Withdrawn) A method of providing a prophylactic therapy against atrial fibrillation, comprising:

performing a cardiac surgical procedure;

inserting an ablation catheter at least partially into the heart, the ablation catheter having a balloon, a portion of the balloon located in the left atrium and a portion of the balloon located in a pulmonary vein;

inflating the balloon with a cryogenic working fluid such that an exterior surface of the balloon is in contact with at least a partial circumference of the portion of the pulmonary vein adjacent the left atrium, the working fluid having a temperature in the range of about -10°C to 100°C.

48. (Withdrawn) The method of claim 47, wherein the cardiac surgical procedure includes valve replacement.

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49. (Withdrawn) The method of claim 47, wherein the cryogenic working fluid is selected from the group consisting essentially of: DMSO, d-limonene, Galden fluid, and a perfluorocarbon-containing fluid.

50. (Withdrawn) The method of claim 47, wherein the inflating includes circulating the working fluid with a source of working fluid having a gear pump.

51. (Withdrawn) The method of claim 47, wherein the balloon has at least one pore formed therein.

52. (Withdrawn) The method of claim 47, wherein the balloon is an annular ring balloon.

53. (Withdrawn) The method of claim 47, further comprising:
inserting a trocar wire capable of rupturing the atrial septum from the femoral vein into the right atrium;
forming a hole using the trocar wire in the atrial septum between the right atrium and the left atrium;
inserting an introducer sheath into the hole, the introducer sheath at least partially contacting the atrial septum;
inserting a guide wire through the introducer sheath into the right atrium and left atrium and further into a pulmonary vein;
disposing the ablation catheter over the guidewire into a volume defined by the joint of the left atrium and the pulmonary vein; and
operating and controlling a heater disposed adjacent or within the introducer sheath, the heater thermally coupled to the atrial septum.

54. (Withdrawn) The method of claim 47, further comprising:

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percutaneously forming an insertion hole in a vessel of a patient;
inserting an introducer sheath into the insertion hole, the introducer sheath at least partially contacting tissue at the insertion hole;
inserting the ablation catheter through the introducer sheath;
disposing the ablation catheter at a predefined location for an ablation therapy; and
operating and controlling a heater disposed adjacent or within the introducer sheath, the heater thermally coupled to the tissue at the insertion hole.